

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0087

Inventors: Recipon et al.

Serial No. 09/705,500

Filing Date: November 3, 2000

Examiner: Canella, Karen A.

Group Art Unit: 1642

Title: A Novel Method of Diagnosing,
Monitoring, Staging, Imaging and
Treating Cancer

Declaration under Rule § 1.131

We, Herve Recipon, Roberto A. Macina, Sei-Yu Chen and
Yongming Sun, hereby declare:

1. We are co-inventors of the above-referenced patent application.

2. As the co-inventors of the above-referenced patent application, we are familiar with the teachings of the above-referenced patent application.

3. The use of Lng108, also known as fy108, as a cancer diagnostic was conceived and reduced to practice in this country at diaDexus, Inc., prior to October 27, 1999 which was located at that time in Santa Clara, California, USA.

4. Specifically, Lng108 relative expression was determined in accordance with our standard Quantitative Polymerase Chain Reaction (QPCR) protocol and outlined in the above-referenced patent application at page 20, line 16 through page 21, line 13; and page 17, line 12 through page 18, line 9 of priority application U.S. Provisional No. 60/163,144, filed on November 4, 1999. These experiments measuring relative levels of Lng108 in cancerous, normal-adjacent, and normal tissues using Polymerase Chain Reaction in real time were performed prior to October 27, 1999.

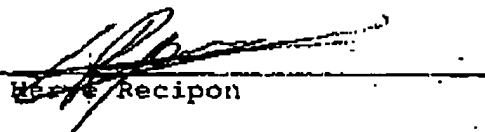
Real-Time quantitative PCR with fluorescent Taqman probes is a quantitation detection system utilizing the 5'-3' nuclease activity of Taq DNA polymerase. The method uses an internal fluorescent oligonucleotide probe (Taqman) labeled with a 5' reporter dye and a downstream, 3' quencher dye. During PCR, the 5'-3' nuclease activity of Taq DNA polymerase releases the reporter, whose fluorescence can then be detected by the laser detector of the Model 7700 Sequence Detection System (PE Applied Biosystems, Foster City, CA, USA).

Amplification of an endogenous control was used to standardize the amount of sample RNA added to the reaction and normalize the Reverse Transcriptase (RT) efficiency. Either cyclophilin, glyceraldehyde-3-phosphate dehydrogenase (GADPH) or 18S ribosomal RNA (rRNA) was used as this endogenous control. To calculate relative quantitation between all samples studied, the target RNA levels for one sample were used as the basis for comparative results (calibrator). Quantitation relative to the calibrator can be obtained using the standard curve method or the comparative method (User Bulletin #2: ABI PRISM 7700 Sequence Detection System).

The tissue distribution, and the level of the target gene for every example in normal and cancer tissue were determined. Total RNA was extracted from normal tissues, cancer tissues, and from cancers and the corresponding matched adjacent tissues. Subsequently, first strand cDNA was prepared with reverse transcriptase and the polymerase chain reaction was done using primers and Taqman probe specific to each target gene. The results are analyzed using the ABI PRISM 7700 Sequence Detector. The absolute numbers are relative levels of expression of the target gene in a particular tissue compared to the calibrator tissue.

5. Attached are copies of laboratory notebook pages 0034-124, 0034-168 and 0049-048 containing QPCR experimental procedures and results for Lng108, also known as fyl08. The actual dates upon which these experiments were performed in this country at diaDexus, Inc., prior to October 27, 1999 which was located at that time in Santa Clara, California, USA, have been redacted from the attached copies. These experiments, all performed prior to October 27, 1999, demonstrated the use of Lng108 as a diagnostic marker for cancer.

We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Roberto A. Macina



Date

Roberto A. Macina

Date

Sei-Yu Chen

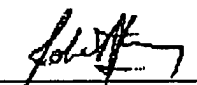
Date

Yongming Sun


Date

We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Herve Recipon

Date

Roberto A. Macina

Date

Sei-Yu Chen

Date

Yongming Sun

Date

We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Herve Recipon

Date

Roberto A. Macina

Date

Sei-Yu Chen

Date

Yongming Sun*August 25, 2004*

Date

p. 7

Ex 108: N=20

Name garcia
 Date _____
 Exam PS4 pgs 1-12 V
 Score 100%
 (Print Panel Log Number _____)

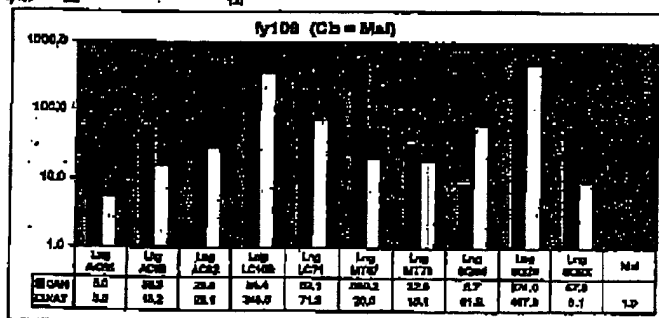
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XX	Master Mix	15.0	750.0
1 GUMMI	Sugar	0.05	3.0
1 GUMMI	Flavor	0.05	3.0
1 GUMMI	Color	0.05	3.0



Matched Tuple Query

Name	Address	Phone	Room	City	Employment Record Dates			Remarks
					From	Present	To	
Long	ACB	1	Off	Washington	1947-1950	1950-1952	1952-1954	Off in and out of service
Long	ACB	2	Off	Washington	1950-1952	1952-1954	1954-1956	Off in and out of service
Long	ACB	3	Off	Washington	1952-1954	1954-1956	1956-1958	Off in and out of service
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Long	ACB	5	Off	Washington	1956-1958	1958-1960	1960-1962	Off in and out of service
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Long	ACB	9	Off	Washington	1964-1966	1966-1968	1968-1970	Off in and out of service
Long	ACB	10	Off	Washington	1966-1968	1968-1970	1970-1972	Off in and out of service
Long	ACB	11	Off	Washington	1968-1970	1970-1972	1972-1974	Off in and out of service
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Long	ACB	19	Off	Washington	1984-1986	1986-1988	1988-1990	Off in and out of service
Long	ACB	20	Off	Washington	1986-1988	1988-1990	1990-1992	Off in and out of service
Long	ACB	21	Off	Washington	1988-1990	1990-1992	1992-1994	Off in and out of service
Long	ACB	22	Off	Washington	1990-1992	1992-1994	1994-1996	Off in and out of service
Long	ACB	23	Off	Washington	1992-1994	1994-1996	1996-1998	Off in and out of service
Long	ACB	24	Off	Washington	1994-1996	1996-1998	1998-2000	Off in and out of service
Long	ACB	25	Off	Washington	1996-1998	1998-2000	2000-2002	Off in and out of service
Long	ACB	26	Off	Washington	1998-2000	2000-2002	2002-2004	Off in and out of service
Long	ACB	27	Off	Washington	2000-2002	2002-2004	2004-2006	Off in and out of service
Long	ACB	28	Off	Washington	2002-2004	2004-2006	2006-2008	Off in and out of service
Long	ACB	29	Off	Washington	2004-2006	2006-2008	2008-2010	Off in and out of service
Long	ACB	30	Off	Washington	2006-2008	2008-2010	2010-2012	Off in and out of service
Long	ACB	31	Off	Washington	2008-2010	2010-2012	2012-2014	Off in and out of service
Long	ACB	32	Off	Washington	2010-2012	2012-2014	2014-2016	Off in and out of service
Long	ACB	33	Off	Washington	2012-2014	2014-2016	2016-2018	Off in and out of service
Long	ACB	34	Off	Washington	2014-2016	2016-2018	2018-2020	Off in and out of service
Long	ACB	35	Off	Washington	2016-2018	2018-2020	2020-2022	Off in and out of service
Long	ACB	36	Off	Washington	2018-2020	2020-2022	2022-2024	Off in and out of service
Long	ACB	37	Off	Washington	2020-2022	2022-2024	2024-2026	Off in and out of service
Long	ACB	38	Off	Washington	2022-2024	2024-2026	2026-2028	Off in and out of service
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Long	ACB	40	Off	Washington	2026-2028	2028-2030	2030-2032	Off in and out of service
Long	ACB	41	Off	Washington	2028-2030	2030-2032	2032-2034	Off in and out of service
Long	ACB	42	Off	Washington	2030-2032	2032-2034	2034-2036	Off in and out of service
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Long	ACB	47	Off	Washington	2040-2042	2042-2044	2044-2046	Off in and out of service
Long	ACB	48	Off	Washington	2042-2044	2044-2046	2046-2048	Off in and out of service
Long	ACB	49	Off	Washington	2044-2046	2046-2048	2048-2050	Off in and out of service
Long	ACB	50	Off	Washington	2046-2048	2048-2050	2050-2052	Off in and out of service
Long	ACB	51	Off	Washington	2048-2050	2050-2052	2052-2054	Off in and out of service
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Long	ACB	68	Off	Washington	2082-2084	2084-2086	2086-2088	Off in and out of service
Long	ACB	69	Off	Washington	2084-2086	2086-2088	2088-2090	Off in and out of service
Long	ACB	70	Off	Washington	2086-2088	2088-2090	2090-2092	Off in and out of service
Long	ACB	71	Off	Washington	2088-2090	2090-2092	2092-2094	Off in and out of service
Long	ACB	72	Off	Washington	2090-2092	2092-2094	2094-2096	Off in and out of service
Long	ACB	73	Off	Washington	2092-2094	2094-2096	2096-2098	Off in and out of service
Long	ACB	74	Off	Washington	2094-2096	2096-2098	2098-2100	Off in and out of service
Long	ACB	75	Off	Washington	2096-2098	2098-2100	2100-2102	Off in and out of service
Long	ACB	76	Off	Washington	2098-2100	2100-2102	2102-2104	Off in and out of service
Long	ACB	77	Off	Washington	2100-2102	2102-2104	2104-2106	Off in and out of service
Long	ACB	78	Off	Washington	2102-2104	2104-2106	2106-2108	Off in and out of service
Long	ACB	79	Off	Washington	2104-2106	2106-2108	2108-2110	Off in and out of service
Long	ACB	80	Off	Washington	2106-2108	2108-2110	2110-2112	Off in and out of service
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Long	ACB	82	Off	Washington	2110-2112	2112-2114	2114-2116	Off in and out of service
Long	ACB	83	Off	Washington	2112-2114	2114-2116	2116-2118	Off in and out of service
Long	ACB	84	Off	Washington	2114-2116	2116-2118	2118-2120	Off in and out of service
Long	ACB	85	Off	Washington	2116-2118	2118-2120	2120-2122	Off in and out of service
Long	ACB	86	Off	Washington	2118-2120	2120-2122	2122-2124	Off in and out of service
Long	ACB	87	Off	Washington	2120-2122	2122-2124	2124-2126	Off in and out of service
Long	ACB	88	Off	Washington	2122-2124	2124-2126	2126-2128	Off in and out of service
Long	ACB	89	Off	Washington	2124-2126	2126-2128	2128-2130	Off in and out of service
Long	ACB	90	Off	Washington	2126-2128	2128-2130	2130-2132	Off in and out of service
Long	ACB	91	Off	Washington	2128-2130	2130-2132	2132-2134	Off in and out of service
Long	ACB	92	Off	Washington	2130-2132	2132-2134	2134-2136	Off in and out of service
Long	ACB	93	Off	Washington	2132-2134	2134-2136	2136-2138	Off in and out of service
Long	ACB	94	Off	Washington	2134-2136	2136-2138	2138-2140	Off in and out of service
Long	ACB	95	Off	Washington	2136-2138	2138-2140	2140-2142	Off in and out of service
Long	ACB	96	Off	Washington	2138-2140	2140-2142	2142-2144	Off in and out of service
Long	ACB	97	Off	Washington	2140-2142	2142-2144	2144-2146	Off in and out of service
Long	ACB	98	Off	Washington	2142-2144	2144-2146	2146-2148	Off in and out of service
Long	ACB	99	Off	Washington	2144-2146	2146-2148	2148-2150	Off in and out of service
Long	ACB	100	Off	Washington	2146-2148	2148-2150	2150-2152	Off in and out of service
Long	ACB	101	Off	Washington	2148-2150	2150-2152	2152-2154	Off in and out of service
Long	ACB	102	Off	Washington	2150-2152	2152-2154	2154-2156	Off in and out of service
Long	ACB	103	Off	Washington	2152-2154	2154-2156	2156-2158	Off in and out of service
Long	ACB	104	Off	Washington	2154-2156	2156-2158	2158-2160	Off in and out of service
Long	ACB	105	Off	Washington	2156-2158	2158-2160	2160-2162	Off in and out of service
Long	ACB	106	Off	Washington	2158-2160	2160-2162	2162-2164	Off in and out of service
Long	ACB	107	Off	Washington	2160-2162	2162-2164	2164-2166	Off in and out of service
Long	ACB	108	Off	Washington	2162-2164	2164-2166	2166-2168	Off in and out of service
Long	ACB	109	Off	Washington	2164-2166	2166-2168	2168-2170	Off in and out of service
Long	ACB	110	Off	Washington	2166-2168	2168-2170	2170-2172	Off in and out of service
Long	ACB	111	Off	Washington	2168-2170	2170-2172	2172-2174	Off in and out of service
Long	ACB	112	Off	Washington	2170-2172	2172-2174	2174-2176	Off in and out of service
Long	ACB	113	Off	Washington	2172-2174	2174-2176	2176-2178	Off in and out of service
Long	ACB	114	Off	Washington	2174-2176	2176-2178	2178-2180	Off in and out of service
Long	ACB	115	Off	Washington	2176-2178	2178-2180	2180-2182	Off in and out of service
Long	ACB	116	Off	Washington	2178-2180	2180-2182	2182-2184	Off in and out of service
Long	ACB	117	Off	Washington	2180-2182	2182-2184	2184-2186	Off in and out of service
Long	ACB	118	Off	Washington	2182-2184	2184-2186	2186-2188	Off in and out of service
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Long	ACB	122	Off	Washington	2190-2192	2192-2194	2194-2196	Off in and out of service
Long	ACB	123	Off	Washington	2192-2194	2194-2196	2196-2198	Off in and out of service
Long	ACB	124	Off	Washington	2194-2196	2196-2198	2198-2200	Off in and out of service
Long	ACB	125	Off	Washington	2196-2198	2198-2200	2200-2202	Off in and out of service
Long	ACB	126	Off	Washington	2198-2200	2200-2202	2202-2204	Off in and out of service
Long	ACB	127	Off	Washington	2200-2202	2202-2204	2204-2206	Off in and out of service
Long	ACB	128	Off	Washington	2202-2204	2204-2206	2206-2208	Off in and out of service
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Long	ACB	131	Off	Washington	2208-2210	2210-2212	2212-2214	Off in and out of service
Long	ACB	132	Off	Washington	2210-2212	2212-2214	2214-2216	Off in and out of service
Long	ACB	133	Off	Washington	2212-2214	2214-2216	2216-2218	Off in and out of service
Long	ACB	134	Off	Washington	2214-2216	2216-2218	2218-2220	Off in and out of service
Long	ACB	135	Off	Washington	2216-2218	2218-2220	2220-2222	Off in and out of service
Long	ACB	136	Off	Washington	2218-2220	2220-2222	2222-2224	Off in and out of service
Long	ACB	137	Off	Washington	2220-2222	2222-2224	2224-2226	Off in and out of service
Long	ACB	138	Off	Washington	2222-2224	2224-2226	2226	

Turn	Theme	GM	net	
7:00	Urg ACB	5.0	5.0	
7:10	Urg ACB	51.5	51.5	paired Mann-Whitney test
7:20	Urg ACB2	24.9	24.9	p-value = 0.746
7:30	Urg ACB2	34.4	34.4	
7:40	Urg LST1	62.1	71.5	
7:50	Urg LST2	58.0	54.0	
8:00	Urg MTT	32.9	35.1	
8:10	Urg BGM	4.7	41.0	
8:20	Urg BGM	57.0	67.5	
8:30	Urg BGM	57.9	6.1	
8:40	Urg		1.0	



DATE:

CONTINUED FROM PAGE 167

*N=20 PCR Assay Worksheet

PCR Target Ligase
 Tissue Load high
 Endogenous Control beta-actin
 Target Primers FIR
 Date of Calibration Mar 7 2004

Name James
 Date 8
 Exp 2240167410
 Order 100/100000
 (Net2 Parcel Lot Number) 2240167410

Ministerial Staff

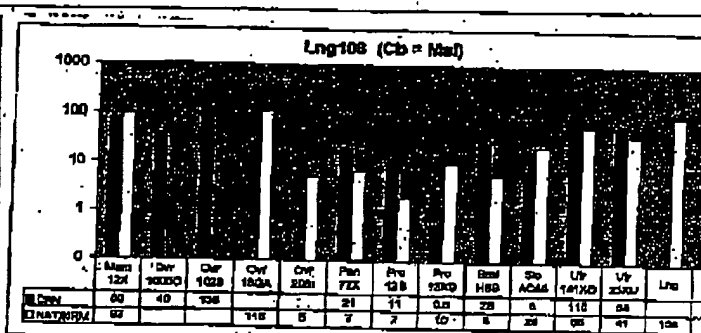
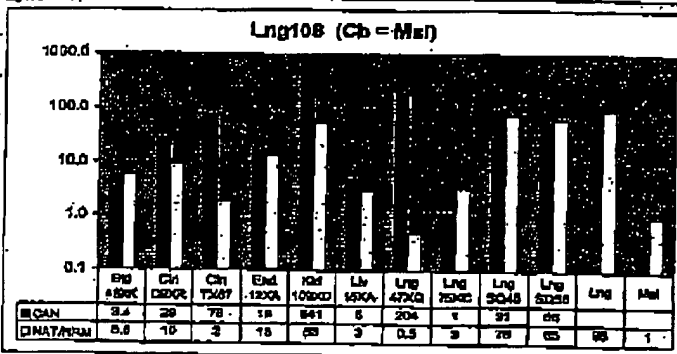
	TARGET & CONTROL	
Water	4.08 (2.55)	24.15
1200ml	15.9	178.6
1200ml	0.08	3.8
1000ml	0.08	3.0
200ml	0.08	3.0
	20	
	10 UL CORNA	

10 UL COPPA

Timeline (as air report below):

Matched Thesis Query

Time	Period	In	Temp	Wind	Rain gauge		
					mm	mm	mm
11	11	11	11	11	11	11	
12	12	12	12	12	12	12	
13	13	13	13	13	13	13	
14	14	14	14	14	14	14	
15	15	15	15	15	15	15	
16	16	16	16	16	16	16	
17	17	17	17	17	17	17	
18	18	18	18	18	18	18	
19	19	19	19	19	19	19	
20	20	20	20	20	20	20	
21	21	21	21	21	21	21	
22	22	22	22	22	22	22	
23	23	23	23	23	23	23	
24	24	24	24	24	24	24	
25	25	25	25	25	25	25	
26	26	26	26	26	26	26	
27	27	27	27	27	27	27	
28	28	28	28	28	28	28	
29	29	29	29	29	29	29	
30	30	30	30	30	30	30	

[illegible]

SCIENTIST SIGNATURE

WITNESS SIGNATURE:

CONTINUED ON PAGE 169

DATE:

DATE:

CONTINUED FROM PAGE 42

N=20 fy108

Objective: to evaluate lung lead fy108 with additional 40 CAN / N1 matched samples.

Protocol:

2.0
 "N=80" PCR Assay Worksheet

PCR Target: fy108 Name: Laura A
 Template Label: muscle Date: 09/08/04
 Endogenous Control: ATPase (used) with Expt: 049/048A
 Target Primers: fy108 (can) fy108 (nat) Order:
 Date of Calibration: muscle North Panel Lot Number: 710-798

Multiplex Mix

	Target's Control
Master	4.52 (500) 244.5
Master Mix	15.0 T950
Primer	0.00 3.0
Template	0.05 3.0
Water	0.05 3.0
	20
	10 uL DNA

Threshold (paste report output):

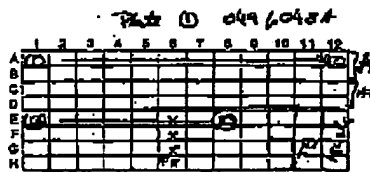
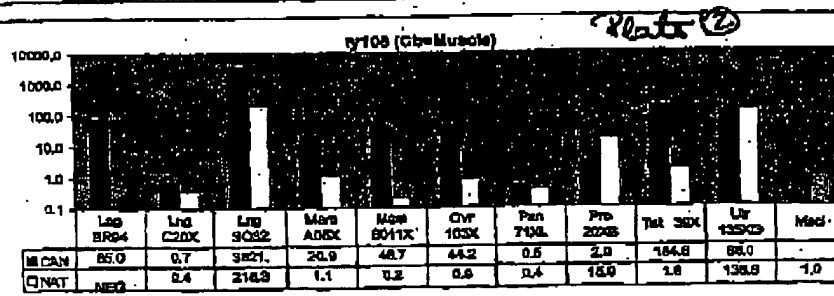
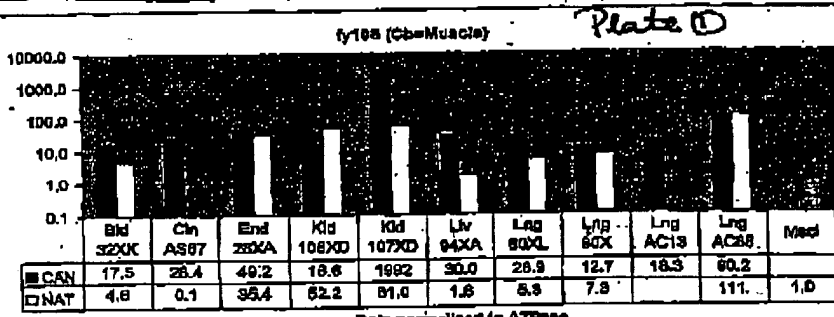


Plate 2 049/048B
 - same setup as plate 1, but different threshold.
 - no template added to wells 25 & 26 on plate 1

Matched Tissue Query

Sample	Panel	Lot	Threshold	CT	Panel	Lot	Threshold	CT	Panel	Lot	Threshold	CT
1	1	1	1	1	1	1	1	1	1	1	1	1
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